

Appln. No. 09/820,339  
Amd. dated August 21, 2006  
Reply to Office Action of June 8, 2005

**REMARKS**

The Office Action and the cited and applied reference have been carefully reviewed. Claim 12 is allowed. Claims 8, 9, 14-18, 25, 27, 30, 31 and 36-41 also presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 14, 25, 27 and 40-41 have been objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. Applicants believe the rejected base claims from which claims 14, 25, 27 and 40-41 are dependent are now allowable in view of the amendments and arguments presented below, and accordingly, rewriting the objected to claims in independent form is believed to be unnecessary.

The examiner's suggestion to amend claim 32 (iii) is not understood as claim 32 was already previously cancelled.

Claims 8, 9, 15-18, 30-31 and 36-39 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The examiner holds that no basis exists in the specification for the negative limitation "with the proviso that said polypeptide tolerogen does not

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consist of residues 1-210 of SEQ ID NO:2" and therefore this negative limitation constitutes new matter. This rejection is respectfully traversed.

MPEP 2173.05(i) states:

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson* 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining.").

The present specification at page 20, paragraph [0072] positively recites Hø1-210 (residues 1-210 of SEQ ID NO:2) and accordingly, applicants are permitted to explicitly exclude this alternative element in the claims as a negative limitation without running afoul of the prohibition of new matter. Claims 8 and 36 are also amended to recite the negative limitation to exclude the sequence of residues 1-210 of SEQ ID NO:2 plus one additional residue added. This additional excluded polypeptide tolerogen is explicitly recited in the present specification in paragraph [0024] bridging pages 9 and 10 ("the polypeptide Hø1-210 (SEQ ID NO:2) in which one or more amino acid residues have been added...").

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

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Claims 36-39 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The examiner finds it ambiguous how a "polypeptide tolerogen [that] does not consist of residues 1-210 of SEQ ID NO:2" can also "consist... of amino acid residues 1-210 of SEQ ID NO:2" as recited in subpart (c) of claim 36. This rejection is respectfully traversed.

The polypeptide tolerogen recited in subpart (c) of claim 36 is directed to a fusion between the polypeptide consisting of residues 1-210 of SEQ ID NO:2 and an additional polypeptide. Accordingly, it is not contradictory to exclude a polypeptide tolerogen which only consists of residues 1-210, i.e., without fusion to an additional polypeptide or without more than one additional residue added to the sequence of residues 1-210 of SEQ ID NO:2. This is made clear by the amendment to claim 36 to specifically recite that "said polypeptide tolerogen does not consist of a sequence consisting of residues 1-210 of SEQ ID NO:2 or said sequence and one additional residue".

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 8, 16-18, 30 and 36-39 have been rejected under 35 U.S.C. §102(b) as being anticipated by Talib et al. (1991). The examiner takes the position that the recitation in the claims of "fused to an additional polypeptide at its N- and/or C-

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terminal end" in claims 8(iv) and 36 is still met by the teachings of Talib. The examiner further states that the sole difference between Talib's sequence and the DNA encoding Hα1-210 of claims 8(iv), 30 and 36 is the mere addition/fusion of the Met start codon residue at the N-terminal end of SEQ ID NO:2, as indicated in Figure 1, which therefore meets "the proviso that said tolerogen does not consist of residues 1-210 of SEQ ID NO:2". This rejection is respectfully traversed.

Claims 8 and 36 are amended to include in the negative limitation the exclusion of a polypeptide tolerogen consisting of residues 1-210 of SEQ ID NO:2 plus one additional residue, which is supported in the present specification as discussed in the written description rejection above. The polypeptide containing the additional Met residue at the N-terminus of Hα1-210 disclosed by Talib is therefore excluded from the present claims by the amendment to claims 8 and 36. Accordingly, Talib does not anticipate the present claims.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their

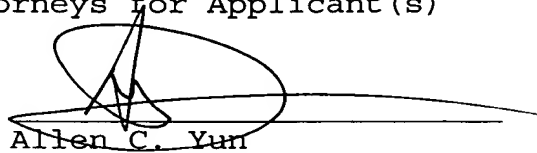
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allowance. Favorable consideration and early allowance are  
earnestly urged.

Respectfully submitted,

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By

A handwritten signature in black ink, appearing to be "Allen C. Yun", is written over a horizontal line. The signature is stylized with a large loop at the beginning.

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